

FIG. 1

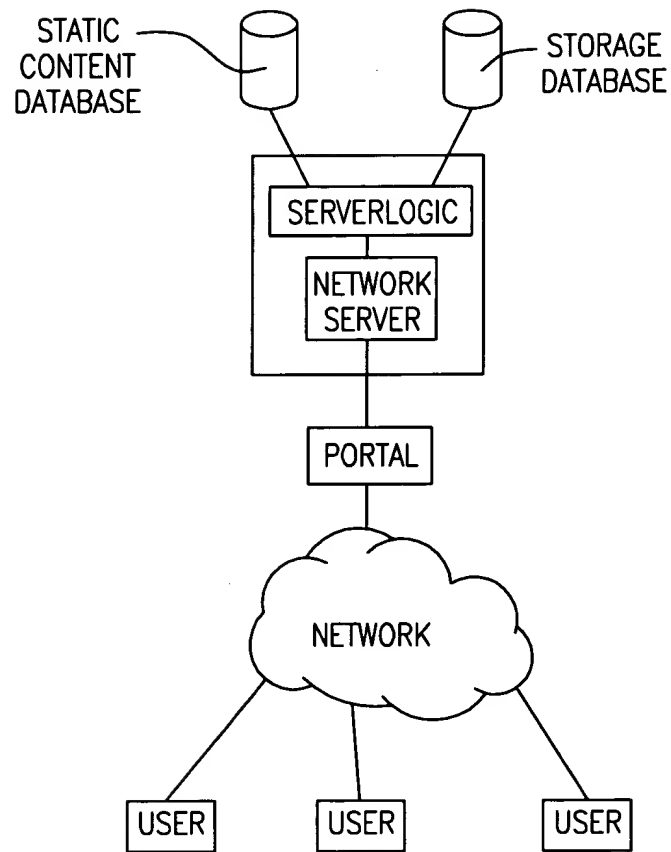


FIG. 2

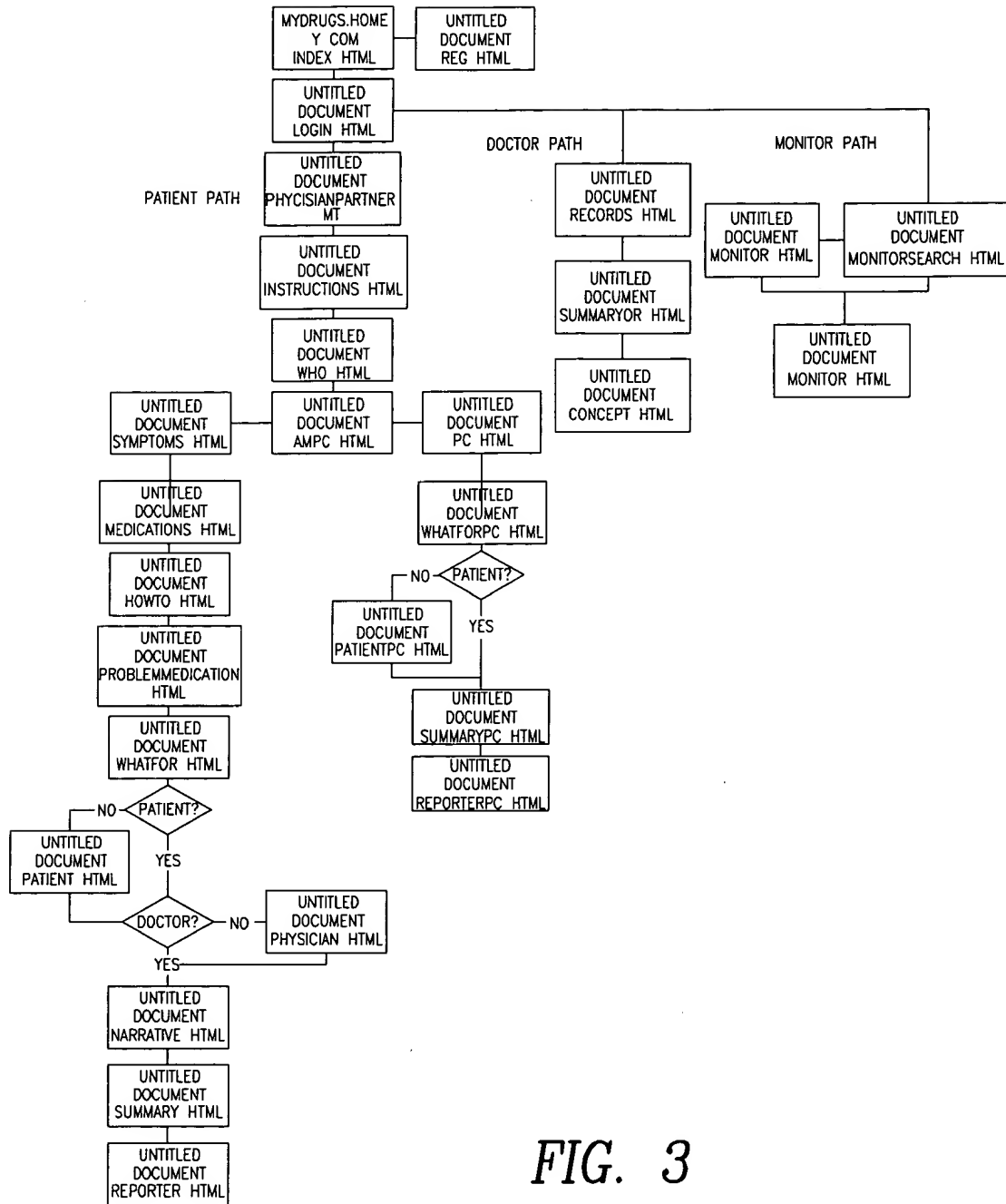


FIG. 3

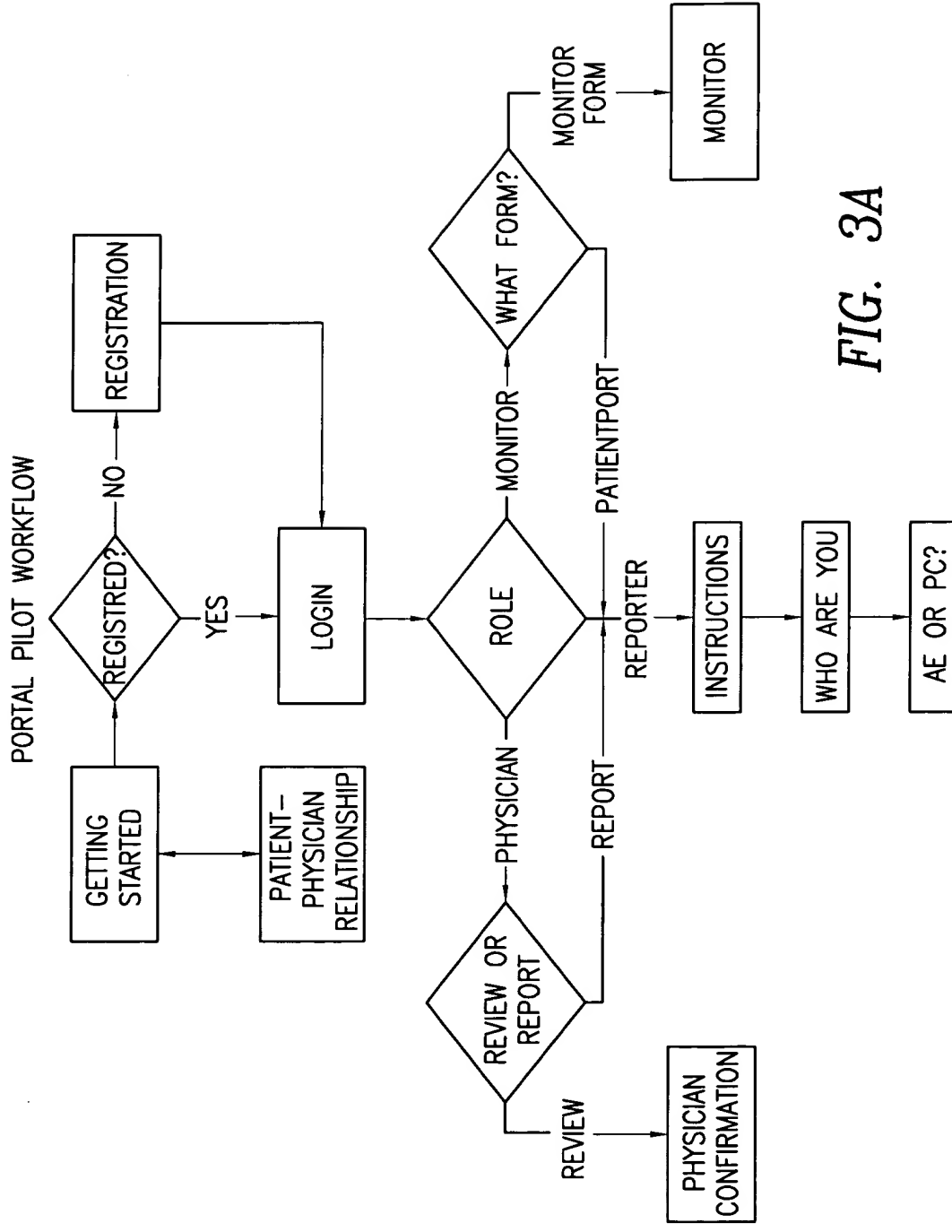


FIG. 3A

AE OR PC
GUIDED REPORTING

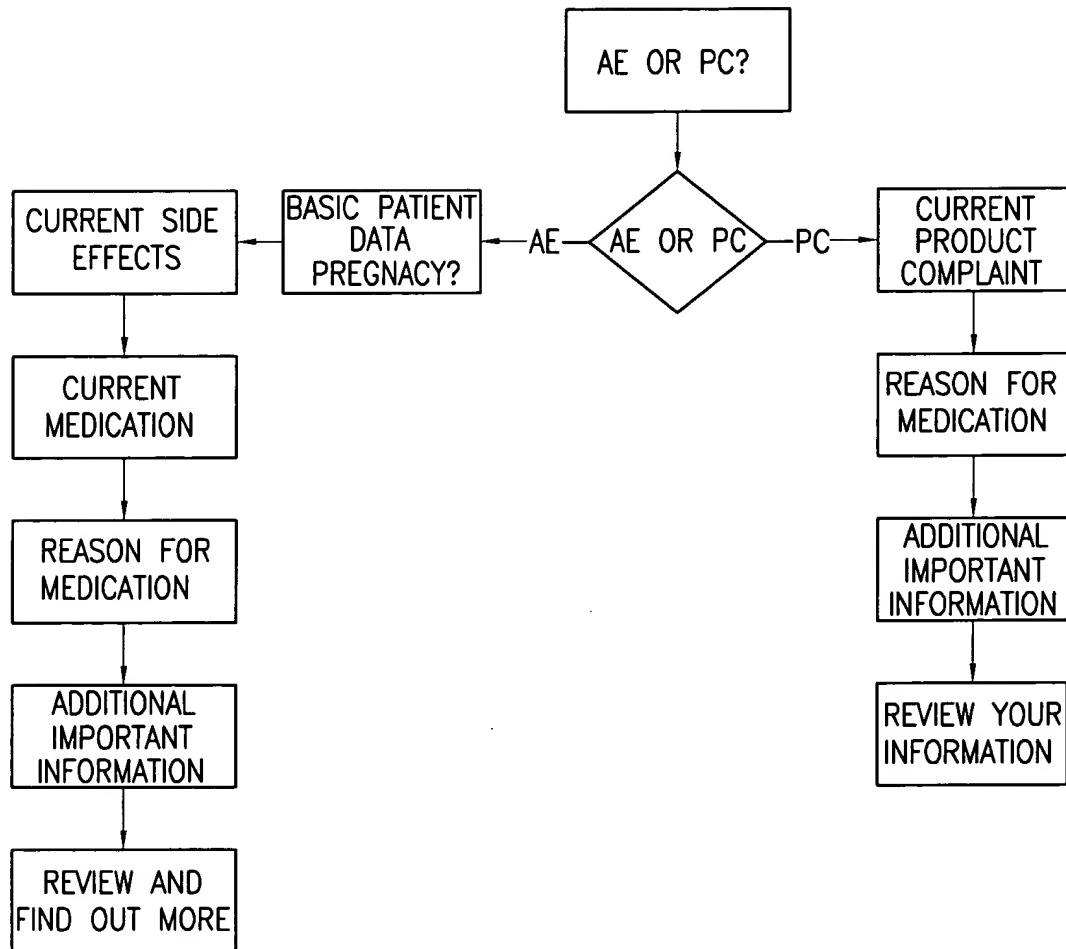


FIG. 3B

PHYSICIAN CONFIRMATION

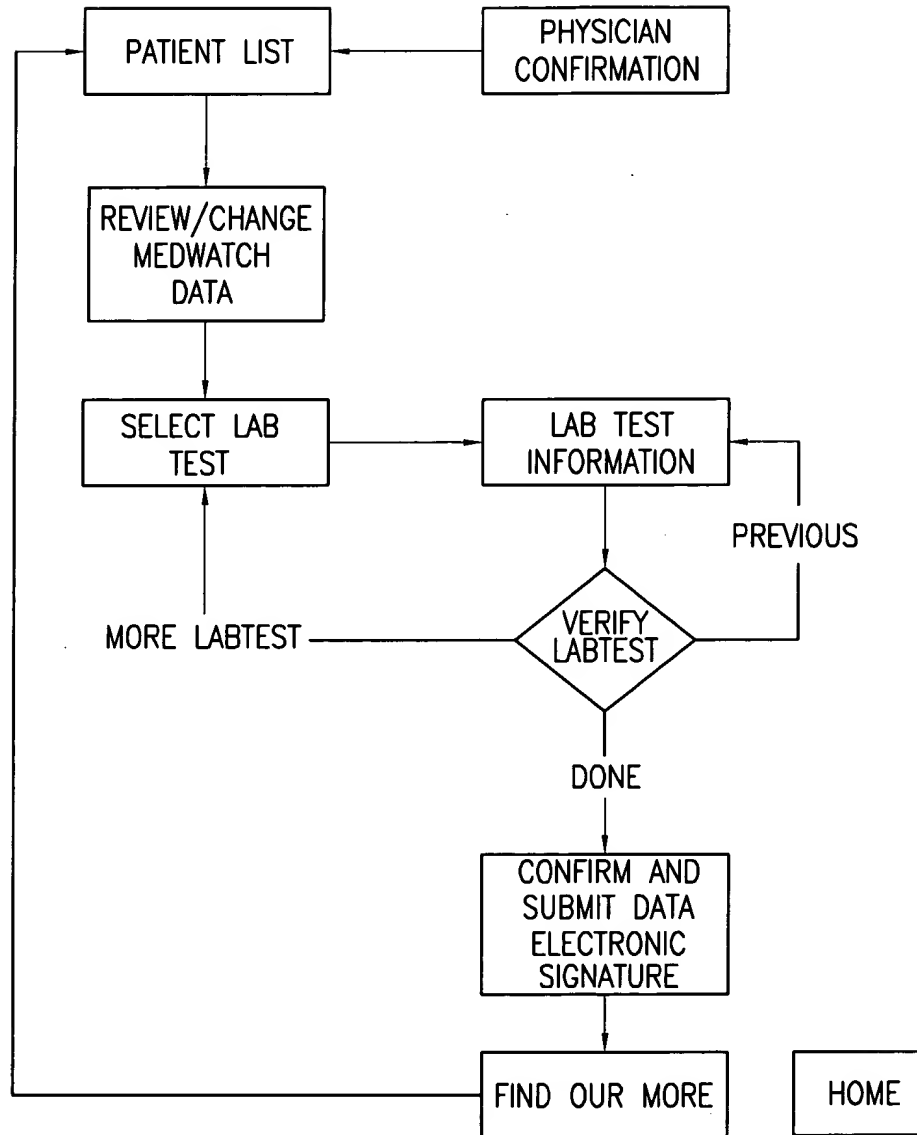


FIG. 3C

MONITOR FORM

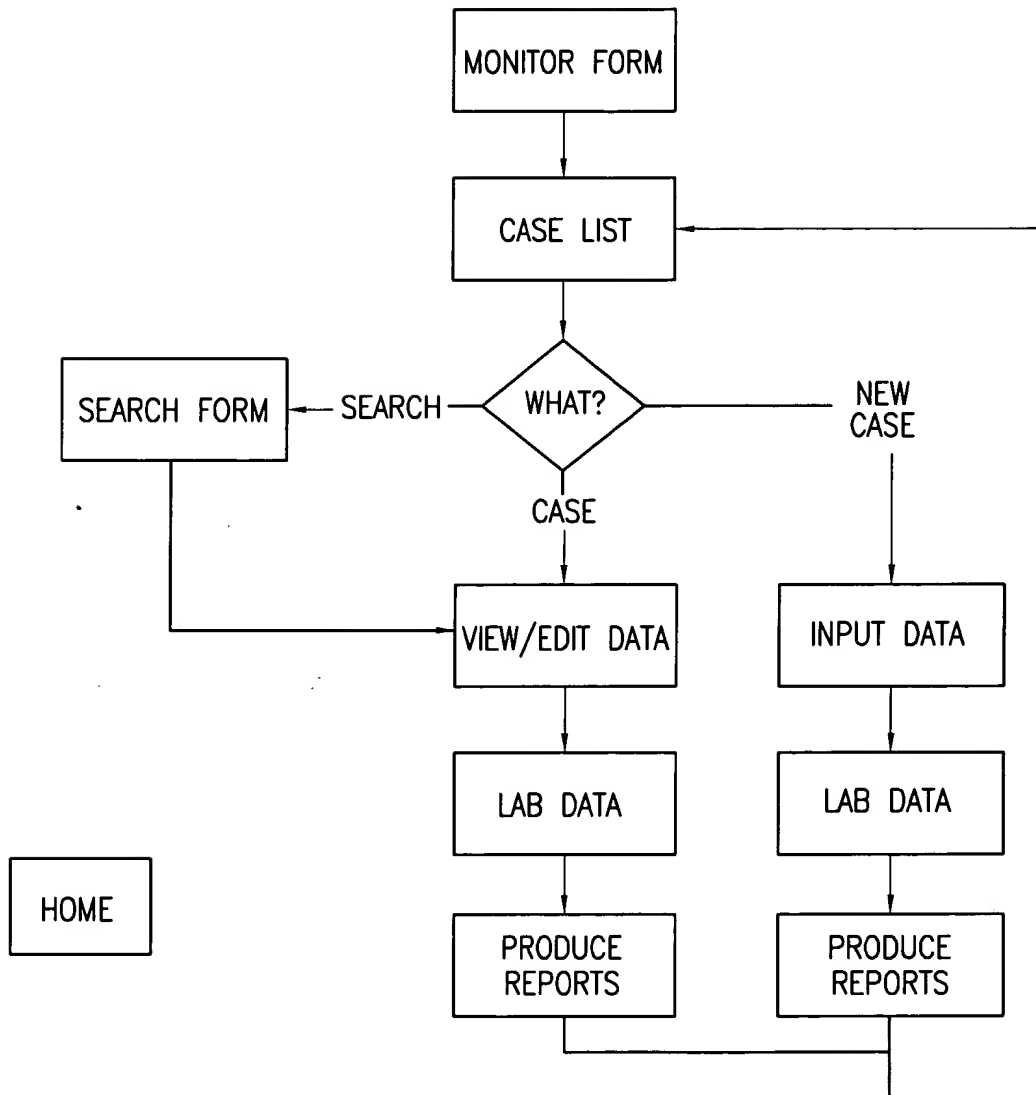


FIG. 3D

CURRENT SIDE EFFECTS

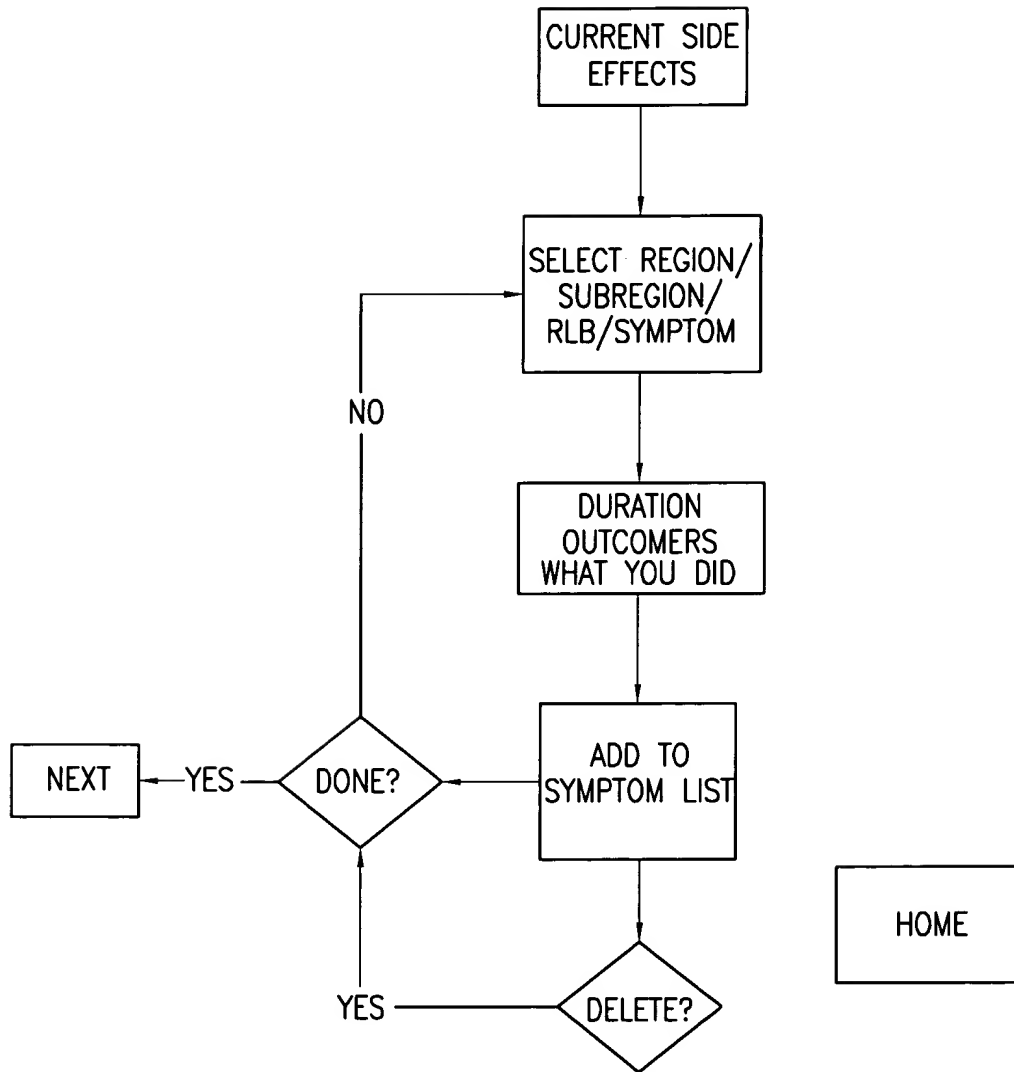


FIG. 3E

CURRENT MEDICATION

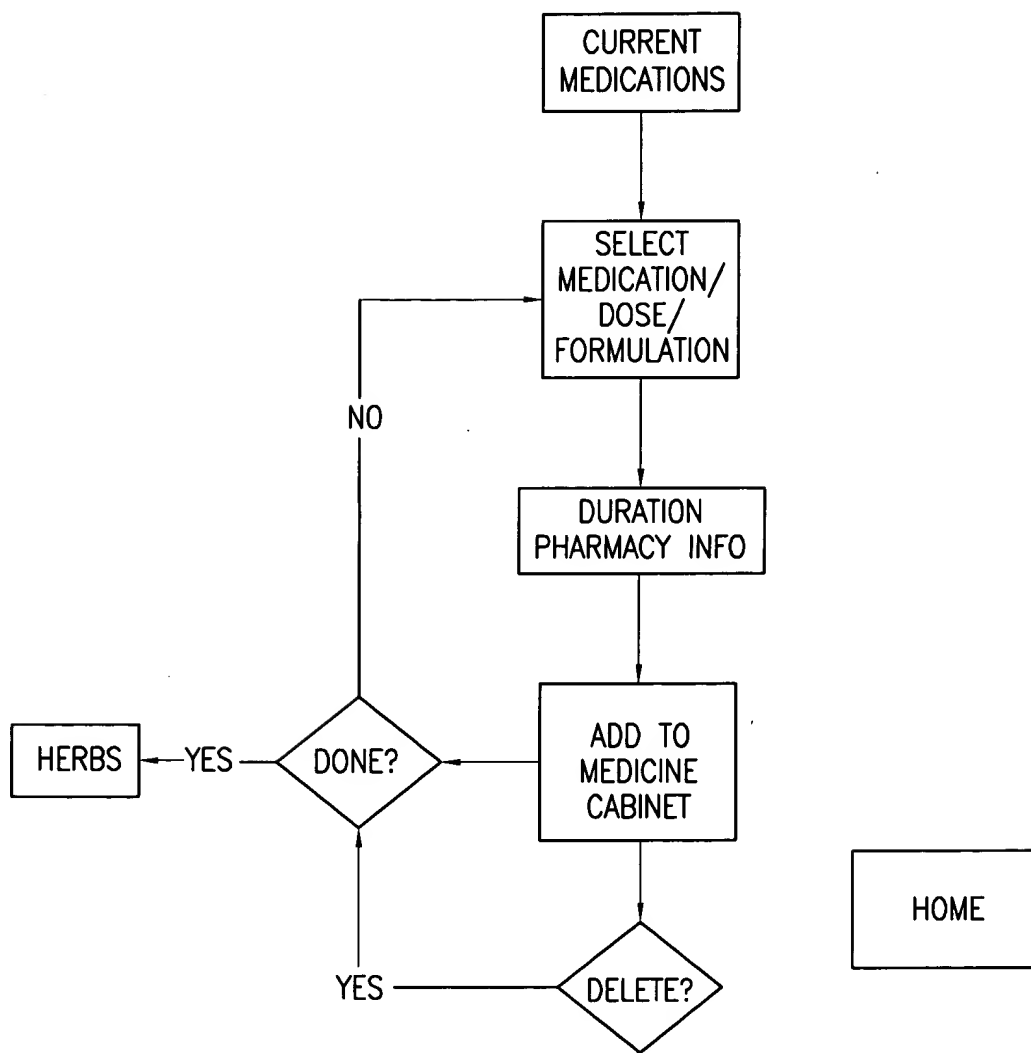


FIG. 3F

HERBS AND NUTRITIONAL SUPPLEMENTS

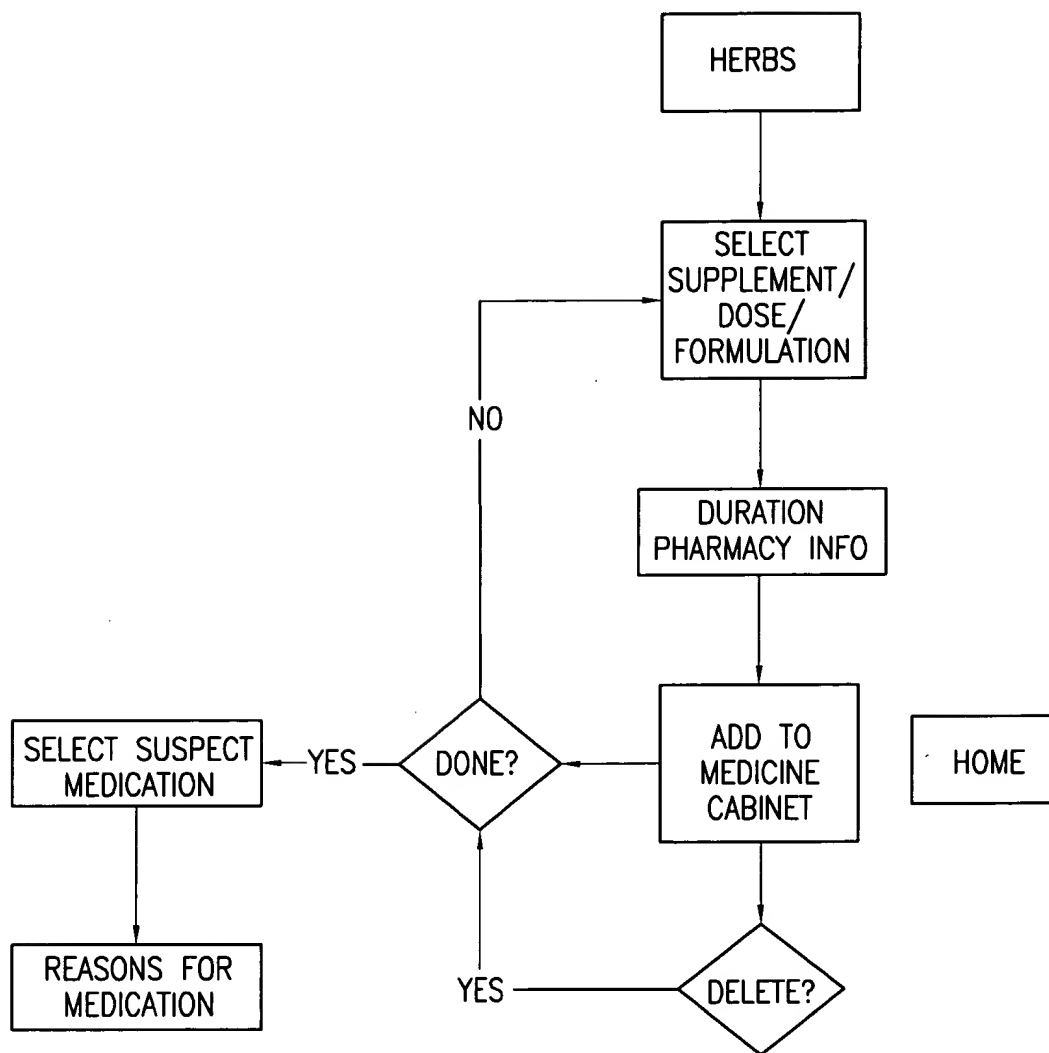


FIG. 3G

REASONS FOR MEDICATION

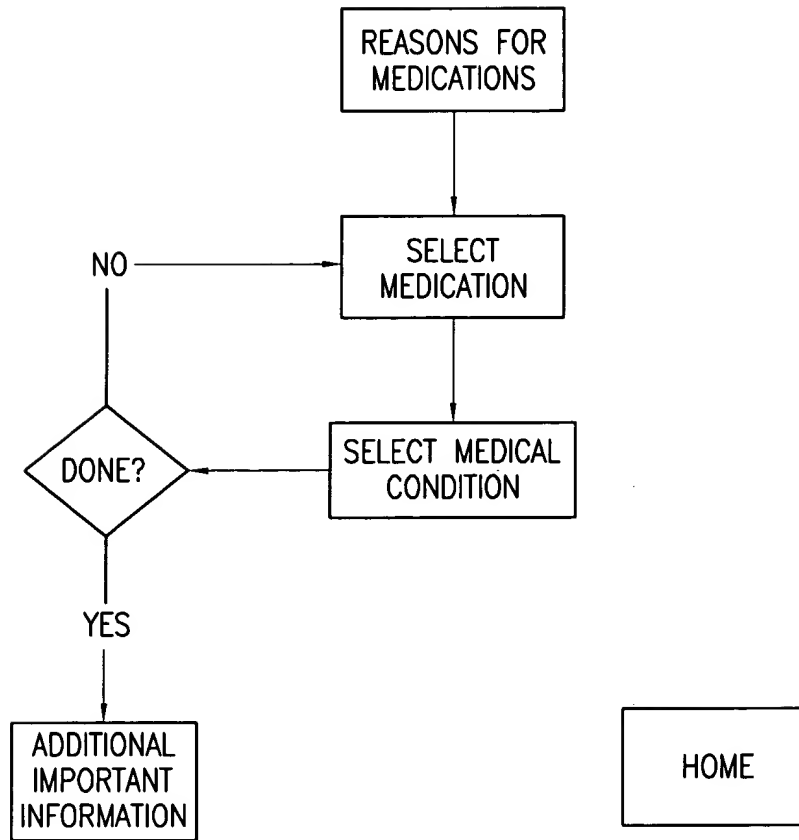


FIG. 3H

ADDITIONAL IMPORTANT INFORMATION

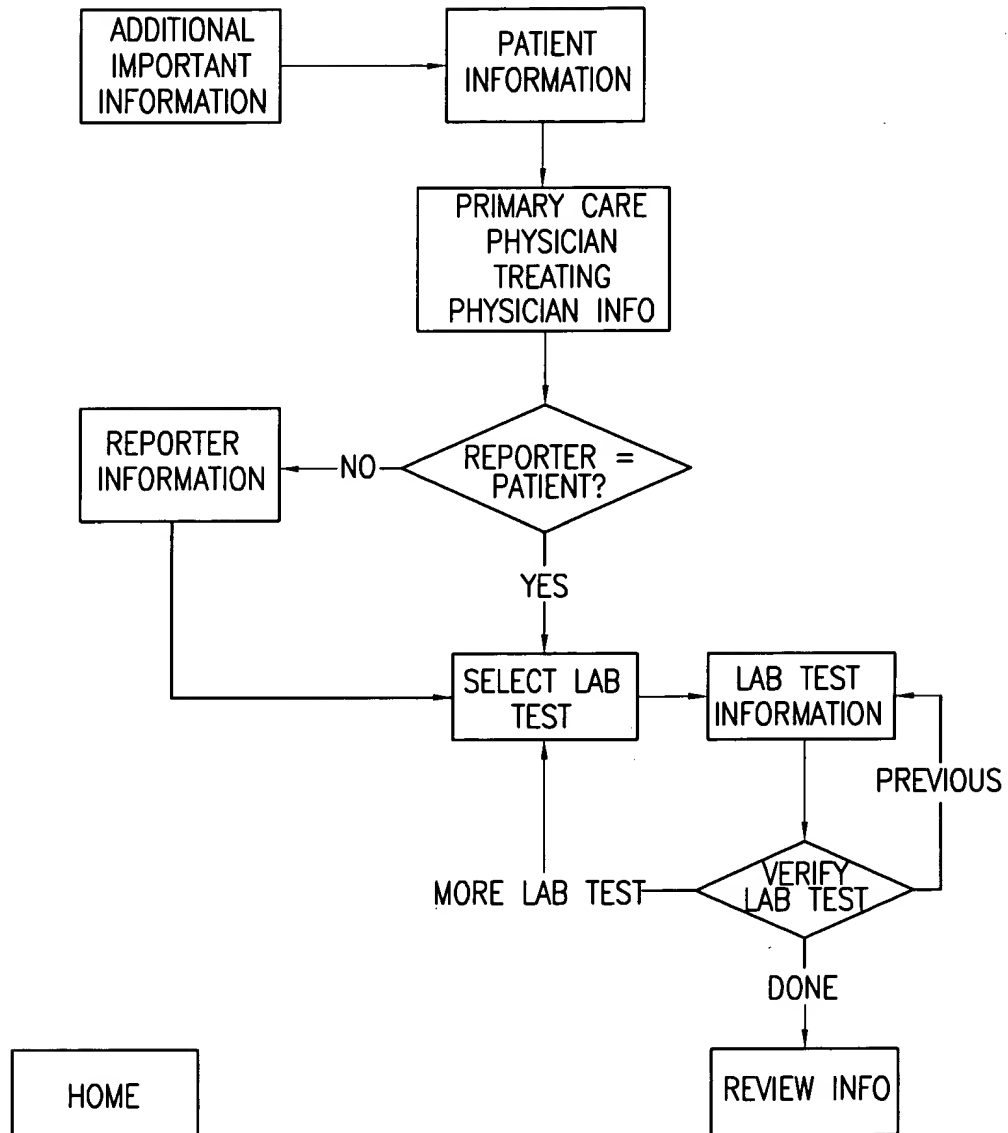


FIG. 3I

REVIEW INFORMATION AND FIND OUT MORE

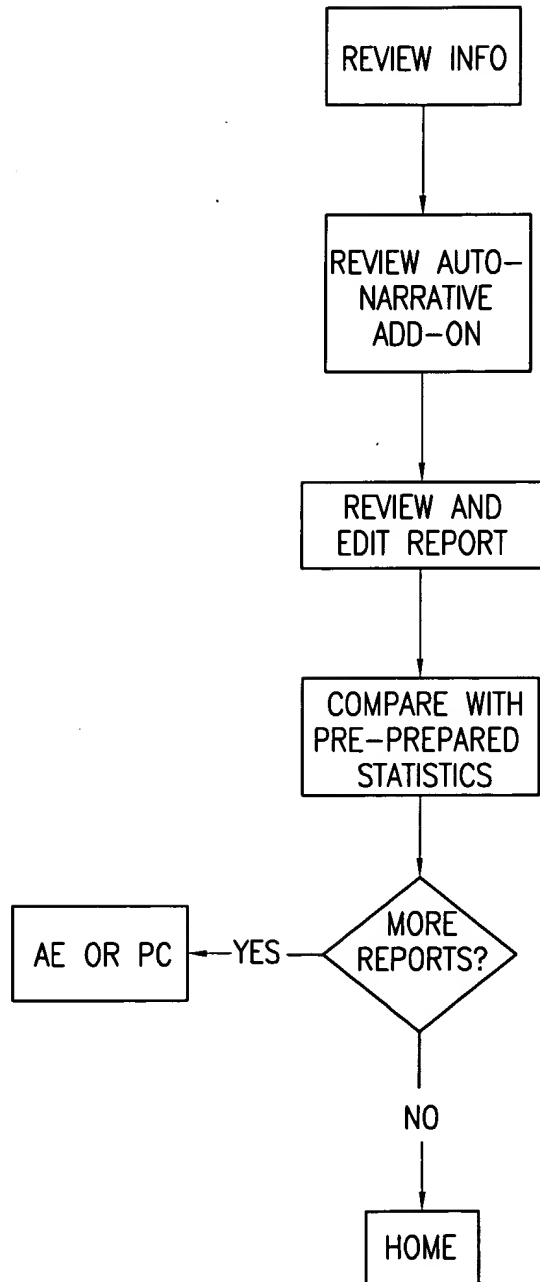


FIG. 3J

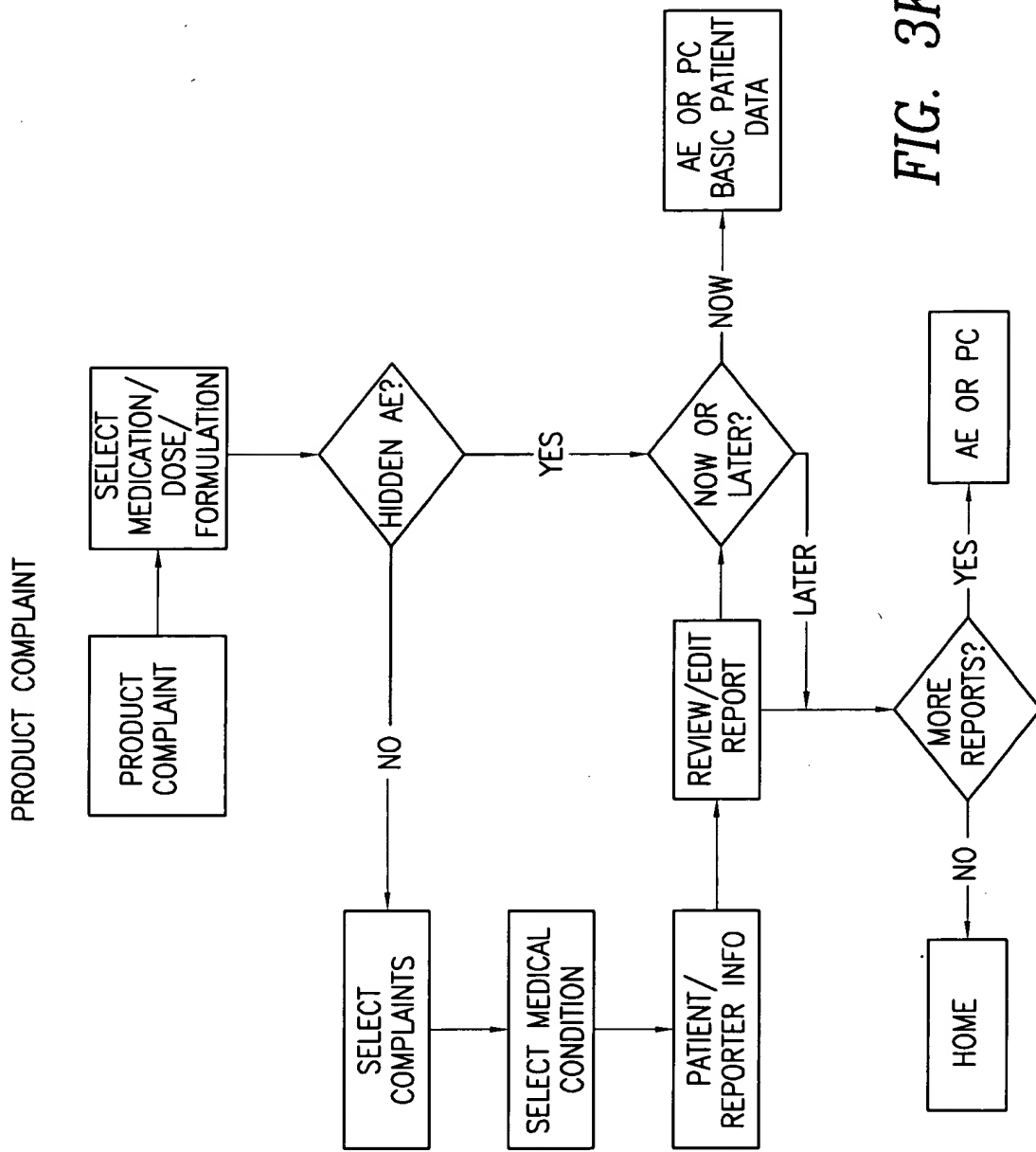
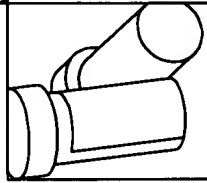


FIG. 3K



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Registration

INFORMED CONSENT

IN ORDER TO COMPLETE THE REPORT, WE MAY NEED TO CONTACT YOUR PHYSICIAN. YOUR CONSENT TO CONTACT your physician is called informed consent. Only your physician and you will see the information you provide us.

☐ Accept (required to proceed)

1 Getting Started Login/Registration instructions

Who are you
Side Effects and/or
Product Complaints

This web portal is super-secure. To see your information, define a User-ID and password and log in. Forget your password? We can recreate it: 1)define a secret question (ex: What is my favorite football team) 2)define a secret answer (ex: the SF 49ers). Together these will identify you.

for this pilot, type the 8 digit registration code printed on your trial card. ?

First Name

Last Name

User ID

Password

Password again

Secret Question

Secret Answer

Phone Number

E-mail

FIG. 4

Getting Started

First-time user? Go to our registration page.

1 Getting Started Login/Registration instructions

Who are you
Side Effects and/or
Product Complaints

You will need some information about your medication. As preparation, please get all your medication bottles, packets and containers.

Our reporting process contains 5 easysteps. At the end, you will receive a summary report for review.

the  symbol provides online help. If you would like to read all the instructions for all the screens click here to download.

userID and Password

User ID

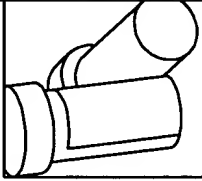
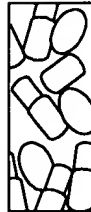
Password

Change your Password?

New Password

Repeat Password

FIG. 5



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Patient-Physician Relationship

1 Getting Started
Login/Registration
instructions

Who are you
Side Effects and/or
Product Complaints

The Patient/Physician Relationship

?

To report your information properly, we have to have your physician confirm it. He will not only help you and us to make drugs safer, he can also help you with your side effect. Please provide us with your and your physician's information so that we can call or write back if we need more information. You can do this at any time by clicking on Registration or you will automatically be asked at the end of the process.

There appears to be an incomplete report in progress from the last time you were logged in. Do you want to recover it?

Clear

Recover

FIG. 6

1 Getting Started
Login/Registration
instructions
Who are you
Side Effects and/or
Product Complaints

Easy steps to report a Side Effect or Adverse Event

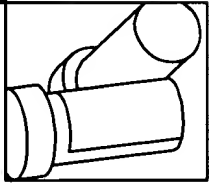

- STEP 1: Side effect or you are experiencing
- STEP 2: Medications you are taking
- STEP 3: Reasons for medication
- STEP 4: Additional important information
- STEP 5: review your report and find out more

Easy steps to report a Product Complaint

- STEP 1: Product complaint
- STEP 2: Reason for Medication
- STEP 3: Additional important information
- STEP 4: Review your report

Next

FIG. 7

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1


Getting Started
Login/Registration
instructions
Who are you
Side Effects and/or
Product Complaints

Who Are You?


Family member/spouse



Patient



Pharmaceutical Representative



Treating Physician

Choose One

Other healthcare Professional

Choose One

Someone else? Who?

Previous

Next

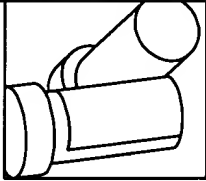

Who Are You?



Help

{helpscreens}

FIG. 8

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Adverse Event or Product Complaint?

1

Getting Started
Login/Registration
instructions

Who are you
Side Effects and/or
Product Complaints

AE

Adverse Reaction or a Side Effect you are having

PC

Complaint about your medication

What Do you Want to Report?

?

Male

Female

Pregnant ☒ YES

Date of Birth (mm-dd-yyyy)

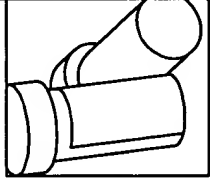
or Age

Height feet inches
(ex: 5 feet 2 inches)

Weight lbs

next

FIG. 9



- Getting Started
- Current Side Effects
 - What Symptoms
 - When Started
 - Ended
 - What Result
 - What you did
- Current Medications
- Reasons for Medication
- Additional Important Information
- Review Info & Find Out More

Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

?

To delete a symptom from highlight it and press
Only when you have finished describing all your symptoms press

Delete

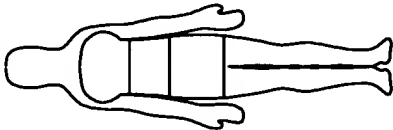
Done

Click the region where the symptoms occurs.

REGION

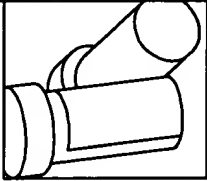

Which area?:

Anus
Bladder
Buttocks
Cervix
Groin
Labia Minora/Majora
Ovaries
Rectum
Uterus
Vagina



or

FIG. 10a

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Adverse Event
define a Symptom

Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

?

Delete

Done

To delete a symptom from highlight it and press

Only when you have finished describing all your symptoms press

Click the region where the symptoms occurs.

REGION

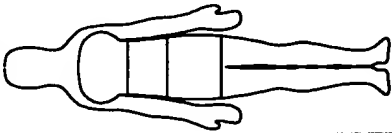
Which area?:

Right-Buttocks

Left-Buttocks

Both-Buttocks

or



- Getting Started
- Current Side Effects
 - What Symptoms
 - When Started
 - Ended
 - What Result
 - What you did
- Current Medications
- Reasons for Medication
- Additional Important Information
- Review Info & Find Out More

FIG. 10b



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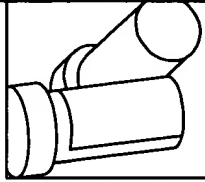

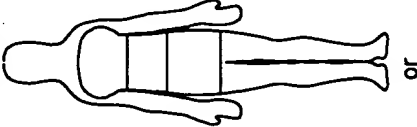


FIG. 10c

Adverse Event
define a Symptom

<p>Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.</p>		<p> <input type="button" value="Delete"/> <input type="button" value="Done"/></p> <p>To delete a symptom from highlight it and press. Only when you have finished describing all your symptoms press</p>	
<p>Click the region where the symptoms occurs.</p> 	<p>REGION Which area?:</p> <p>Buttocks</p>	<p>SYMPTOM What symptom?:</p> <p>Hip Pain</p>	<p>When did it start? <input type="text"/> (mm-dd-yyyy) When did it end <input type="text"/> (mm-dd-yyyy) OR How Long did it last? <input type="text"/> YEAR <input type="text"/> Y it is still there? <input type="checkbox"/> yes <input type="checkbox"/> no</p> <p>RESULT What was the result of this event? <input type="checkbox"/> Hospitalized under 24 hours <input type="checkbox"/> Hospitalized over 24 hours <input type="checkbox"/> Disability</p> <p><input type="checkbox"/> Did nothing <input type="checkbox"/> Consulted a Physician <input type="checkbox"/> Stopped Medication <input type="checkbox"/> Reduced dose to <input type="text"/> <input type="checkbox"/> Switched Medication to <input type="text"/> <input type="checkbox"/> Did it help? <input type="checkbox"/> Took medication again and effect came back <input type="checkbox"/> Took something for it. What? <input type="text"/></p>

1 Getting Started

2 Current Side Effects
What Symptoms
When Started Ended
What Result
What you did

3 Current Medications

4 Reasons for Medication

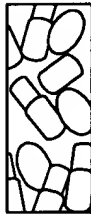
5 Additional Important Information

6 Review Info & Find Out More

<u>General Body</u>		<input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Intervention Needed <input type="checkbox"/> Life-Threatening <input type="checkbox"/> Died <input type="text"/> (mm-day-yyyy) Other <input type="checkbox"/> <input type="text"/>	Did it help? <input type="checkbox"/> YES Did something else <input type="text"/>
Add Symptom to list			

[Help](#)
[{helpscreens}](#)

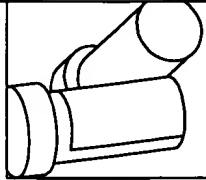
FIG. 10d



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What Medication Are You Taking?
Medication



1 Getting Started

2 Current Side Effects

3 Current Medications

Medications
Herbs and Supplements
suspect Medication

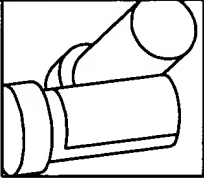

4 Reasons for Medication

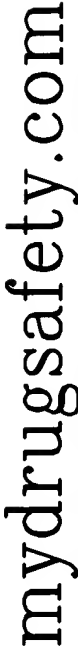
5 Additional Important Information

6 Review Info & Find Out More

Your medicine Cabinet	
	<div>To delete a medication from the list highlight it and press when your current Medication list is complete press</div> <div>Delete</div> <div>Done</div>
Medication: Lamisil Dose: 1% Formulation: CREAM Frequency: 0 times a Day	<div>How Long did it last? [] [] YEAR [] []</div> <div>Start [] [] (mm-dd-yyyy) End [] [] (mm-dd-yyyy)</div> <div>Still on it optional info Lot # of drug? if present [] [] [] []</div> <div>What Pharmacy did you purchase it at? Name [] [] [] [] [] [] Zipcode [] [] [] [] [] []</div> <div>Add to Medicine Cabinet</div>

FIG. 11



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What Medication Are You Taking?

Suspect Medication

1 Getting Started

2 Current Side Effects

3 Current Medications Medication Herbs and Supplements suspect Medication

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

Please select the medication(s) that you think may have caused the event>

Your Current Medications Are

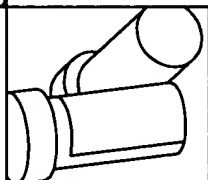
☒ Lamisil

Previous

Next

?

FIG. 12



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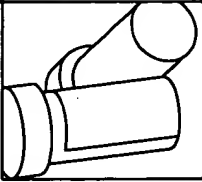
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What Medication Are You Taking?
Herbs or Nutritional Supplements

- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
Medications
Herbs and Supplements
Problem Medication
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

<p>?</p> <p>Tell us what herbs or other supplements you are taking. click letter to choose from list. ABCDEFGHIJKLM NOPQRSTUVWXYZ</p> <p>Pick one:</p> <p>Select a medication ▼</p> <p>Not on the list? Enter below</p> <p>What Dose</p> <p>Select a dose ▼</p> <p>Times a day ▼</p> <p>What Formulation?</p> <p>what formulation ▼</p>		<p>Your Current Herbs</p> <p>Your Current Medications &medicine1 &medicine1</p>	
<p>HOW LONG</p> <p><input type="checkbox"/> number of days ▼</p> <p>Start mm-dd-yy</p> <p>End mm-dd-yy</p> <p><input type="checkbox"/> Still on it optional info</p> <p>Lot # of supplement? if present</p> <p>What Pharmacy did you purchase it at?</p> <p>name</p> <p>zipcode</p>		<p>Add to Medicine Cabinet</p> <p>Need To delete a medication from your current list? Highlight it and press</p> <p>Delete</p> <p>when your current medication list is complete press</p> <p>Done</p>	

FIG. 13



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Adverse Event

What Are You Taking Your Medication For?

1 Getting Started

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

Help

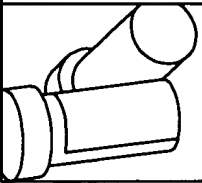
{helpscreens}

What condition are you taking your medication for? click on your medication and a list of its associated condition/disease will appear. select the appropriate one. Repeat for each medicine in the list. ?

Your Medication List				Medical Condition
Medication	Formulation	Dose	Frequency (Times a day)	
Lamisil	Cream	1%	4	<div>Select only one</div> <div>Not on this list?...Enter below</div> <div>1</div>
<div>Previous</div> <div>Next</div>				

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FIG. 14A



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Adverse Event Product Complaint
Check your record

this Report

1 Getting Started

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

Review narrative
Review Your Info
Other Similar Reports
to the FDA

A - 30year old pregnant 1 patient, weighing 110 pounds, height 5 feet 6 inches, was taking lamisil 1% CREAM 4 Times a day since 07-01-2000, since [how long] [or continuing}, for [indication/condition], reportedly experienced an event [verbatim or reported' term/symptom (R/L/B)] on [date]. This report was received by [pharmaceutical company or GSS] on [date] from [reporter name].
The patient was also taking [prescription medication, over-the-counter or nutraceutical products: concomitant drug 1 (dose, formulation, number of times/day, how long or continuing) for (indication/condition); concomitant drug 2 (dose, formulation, number of times/day, how long

Anything to add?

Blablabla

Previous

Next

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Help

FIG. 15



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Review Your Record
Summary Report
pat1 patlast



Review and Edit your report,

Report is complete

1 Getting Started

Type over text to edit and only when complete press
A. Patient Information

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

A. Adverse Event Results

☐ Died On [] (mm-day-yyyy)

☐ Hospitalized Less than 24 Hrs

☐ Hospitalized over 24 Hrs

☒ Disability

☐ Congenital Anomaly

☐ Intervention needed

☐ Life threatening

☐ Other []

Date of Event [] (mm-dd-yyyy)

Date of Report [01-23-2001] (mm-dd-yyyy)

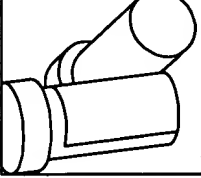
FIG. 16a

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FIG. 16b



PatientPort



HOME | Wer wir sind | Erstmaliger Benutzer | Datenschutz | Logout

Arzneimittel–Nebenwirkungen
definieren Sie Das Symptom

Start

1 Login/Registrierung
Bedienungsanleitung
wer sind Sie?

Arzneimittel–
Nebenwirkung oder
Beschwerde über das
Arzneimittel

2 Arzneimittel–
Nebenwirkung

Ihre Symptome
Beginn und Ende
Direkte Auswirkungen
Gegenreaktionen

3 Ihre
Medikamente

Medikamente
Andere Medikamente
Heilkräuter & Vitamine

4 Weshalb
nehmen Sie

FIG. 16C

<p>Wir bitten Sie, im folgenden Ihre Arzneimittel–Nebenwirkungen zu Beschreiben. klicken Sie bitte eine Körperebene an und es wird eine liste von Sub–Regionen erscheinen. Definieren Sie Ihr Symptom, indem Sie zuerst den genauen Ort bestimmen und dann ein symptom aus der präsentierten liste auswählen. Durch Anklicken der Figur können sie nachher weitere Regionen auswählen.</p>		<p>Ihre Symptome Augen, verschwommene Sicht Augen, verengte Pupillen</p>	
<p>Klicken Sie bitte die Region, in der ihr Symptom sich aussert</p>	<p>KOPF Wählen Sie die Region?</p>	<p>DAUER</p>	<p>WAS UNTERNAHMEN SIE DAGEGEN?</p>
	<p>AUGEN</p>	<p>Beginn des Symptoms mm–dd–yy Ende des Symptoms mm–dd–yy Wie lange dauerte es? Tage 1 Besteht das Symptom immer noch? <input type="checkbox"/> JA</p>	<p><input type="checkbox"/> Nichts <input type="checkbox"/> Konsultierte einen Arzt <input type="checkbox"/> Stoppte die medikamenten Einnahme Reduzierte die medikamenten Dosis auf <input type="checkbox"/> Wechselte das Medikament auf</p>
		<p>AUSWIRKUNG DES SYMPTOMS Hatte das symptom direkte medizinische Auswirkungen, wie</p>	<p>Half es? <input type="checkbox"/> JA <input type="checkbox"/> Nahm das Medikament wieder und der Effekt erschien wieder</p>

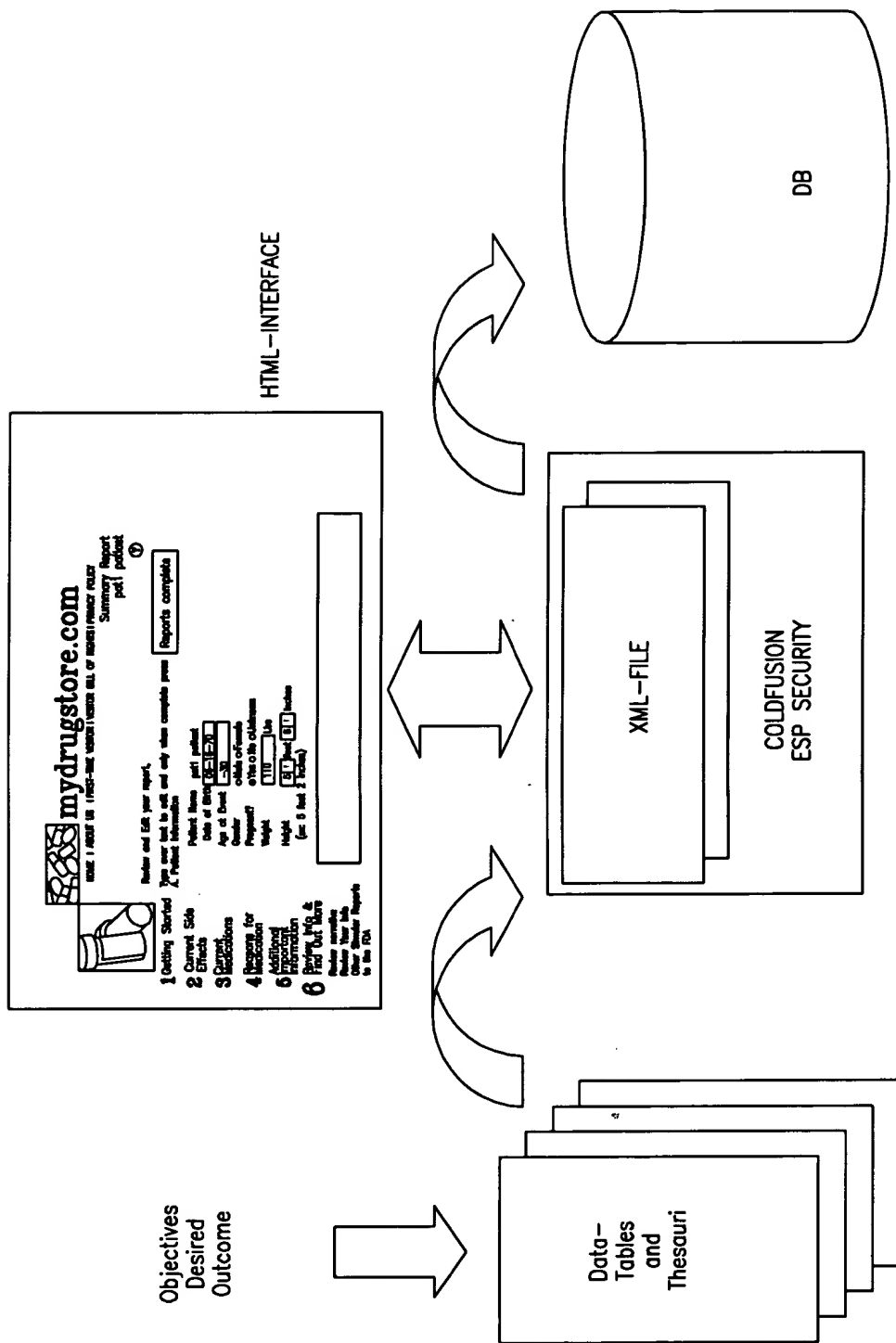


FIG. 17

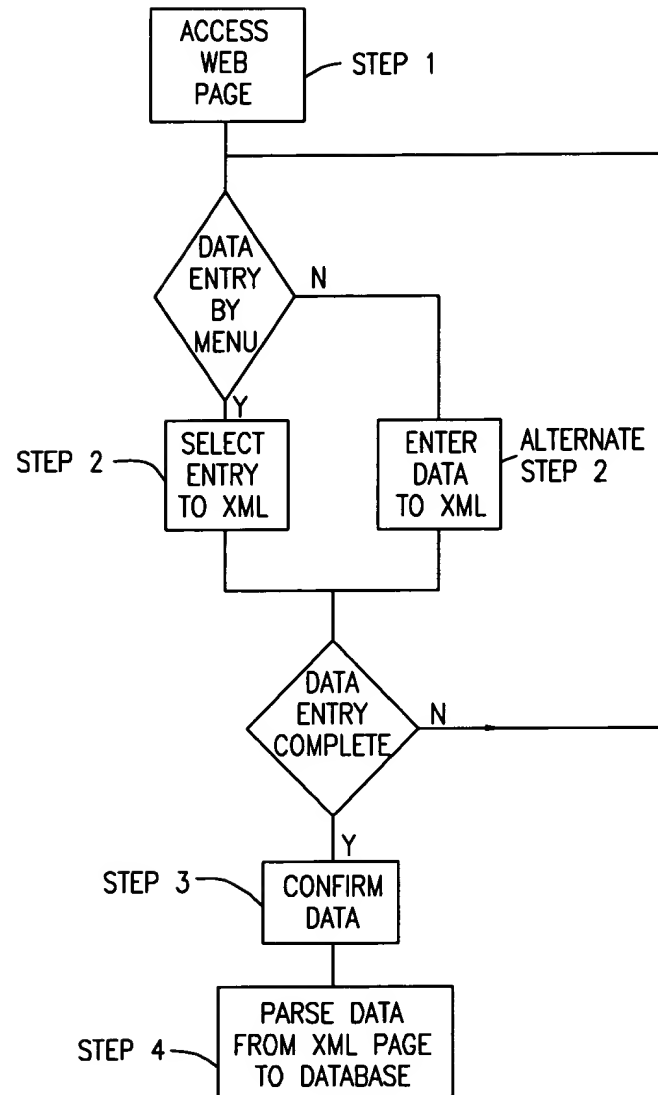


FIG. 18